

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 2 of 22

**Amendments To The Claims:**

The text of all pending claims (including withdrawn claims) is set forth below. Cancelled and not entered claims are indicated with claim number and status only. The claims as listed below show added text with underlining and deleted text with strikethrough. When strikethrough cannot easily be perceived, or when five or fewer characters are deleted, [[double brackets]] are used to show the deletion. The status of each claim is indicated with one of (original), (currently amended), (cancelled), (withdrawn), (new), (previously presented), or (not entered).

**Listing of Claims:**

1. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

- (a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;
- (b) a subcoating layer comprising an alkaline agent; and
- (c) an enteric coating material layered over said subcoating layer; wherein said substrate is characterized in that said substrate does not include an alkaline agent.

2. (Withdrawn) The composition of claim 1, wherein lansoprazole comprises lansoprazole base.

3. (Withdrawn) The composition of claim 1, wherein said substrate features:

- (i) a neutral core; and
  - (ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;
- such that the composition is in a form of a pellet.

{B0544290: 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 3 of 22

4. (Withdrawn) The composition of claim 3, wherein said neutral core comprises a non pareil.

5. (Withdrawn) The composition of claim 4, wherein said non-pareil has a range in a size of from about 300 to about 1000 microns.

6. (Withdrawn) The composition of claim 3, wherein said active coating includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC), or a mixture thereof.

7. (Canceled)

8. (Withdrawn) The composition of claim 3, wherein said active coating comprises at least one surfactant selected from the group consisting of Tween 80 or sodium lauryl sulfate.

9. (Canceled)

10. (Withdrawn) The composition of claim 3, wherein said active coating further comprises at least one filler.

11. (Withdrawn) The composition of claim 10, wherein said at least one filler comprises a suitable grade of lactose.

12. (Withdrawn) The composition of claim 3, wherein said active coating further comprises an aqueous solvent.

{B0544290: 11}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 4 of 22

13. (Withdrawn) The composition of claim 1, wherein said alkaline agent in said subcoating layer comprises an organic basic salt.

14. (Withdrawn) The composition of claim 13, wherein said organic basic salt includes at least one of sodium stearate.

15. (Withdrawn) The composition of claim 1, wherein said alkaline agent in said subcoating layer comprises an inorganic basic salt.

16. (Withdrawn) The composition of claim 1, wherein said subcoating layer includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and hydroxypropyl cellulose (HPC), or a mixture thereof.

17. (Canceled)

18. (Withdrawn) The composition of claim 1, wherein said subcoating layer comprises at least one surfactant selected from the group consisting of Tween 80 or sodium lauryl sulfate.

19. (Canceled)

20. (Withdrawn) The composition of claim 1, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

21. (Withdrawn) The composition of claim 1, wherein said enteric coating material further comprises a plasticizer selected from the group consisting of a citric acid

{B0544290: 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 5 of 22

ester and a phthalic acid ester.

22. (Canceled)

23. (Withdrawn) The composition of claim 1, wherein said substrate is an active core for containing lansoprazole.

24. (Withdrawn) The composition of claim 23, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.

25. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;

(b) a subcoating layer for coating said substrate, said subcoating layer consisting essentially of an alkaline agent, a cellulosic polymer, a filler, a surfactant and a solvent; and

(c) an enteric coating material layered over said subcoating layer.

26. (Currently amended) A method for administering a therapeutically effective amount of lansoprazole as sole active ingredient to a subject comprising: administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof, wherein said substrate is characterized in that said substrate does not include an alkaline agent.

(b) a subcoating layer for coating said substrate, said subcoating layer consisting essentially of an alkaline agent, sodium stearate, a cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and

{B0544290; 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 6 of 22

hydroxypropyl cellulose (HPC), or a mixture thereof, a filler, a surfactant selected from the group consisting of polysorbate 80 and sodium lauryl sulfate, and a solvent; and

(c) an enteric coating material layered over said subcoating layer.

27. (Currently amended) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof as sole active ingredient, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer  
~~wherein said substrate is characterized in that said substrate does not include an alkaline agent.~~

28. (Original) The method of claim 27, wherein lansoprazole comprises lansoprazole base.

29. (Previously presented) The method of claim 27, wherein said substrate features:

(i) a neutral core; and  
(ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;  
such that the composition is in a form of a pellet.

30. (Original) The method of claim 29, wherein said neutral core comprises a non pareil.

{B0544290; 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 7 of 22

31. (Original) The method of claim 30, wherein said non-pareil has a range in a size of from about 300 to about 1000 microns.

32. (Previously presented) The method of claim 29, wherein said active coating includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC), or a mixture thereof.

33. (Canceled)

34. (Currently amended) The method of claim 29, wherein said active coating comprises at least one surfactant selected from the group consisting of Tween polysorbate 80 ~~or and~~ sodium laurel sulfate.

35. (Canceled)

36. (Previously presented) The method of claim 29, wherein said active coating further comprises at least one filler.

37. (Currently amended) The method of claim 36, wherein said at least one filler comprises ~~a suitable grade of~~ lactose monohydrate.

38. (Previously presented) The method of claim 29, wherein said active coating further comprises an aqueous solvent.

39. (Previously presented) The method of claim 27, wherein said alkaline agent in said subcoating layer comprises an organic basic salt.

{B0544290: 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 8 of 22

40. (Currently amended) The method of claim 39, wherein said organic basic salt ~~includes at least one of~~ comprises sodium stearate.

41. (Previously presented) The method of claim 27, wherein said alkaline agent in said subcoating layer comprises an inorganic basic salt.

42. (Previously presented) The method of claim 27, wherein said subcoating layer includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and hydroxypropyl cellulose (HPC), or a mixture thereof.

43. (Canceled)

44. (Currently amended) The method of claim 27, wherein said ~~active~~ coating subcoating layer comprises at least one surfactant selected from the group consisting of ~~Tween~~ polysorbate 80 or and sodium lauryl sulfate.

45. (Canceled)

46. (Previously presented) The method of claim 27, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

47. (Previously presented) The method of claim 27, wherein said enteric coating material further comprises a plasticizer selected from the group consisting of a citric acid ester and a phthalic acid ester.

{80544290; 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 9 of 22

48. (Canceled)

49. (Original) The method of claim 27, wherein said substrate is an active core for containing lansoprazole.

50. (Original) The method of claim 49, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.

51. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

- (a) a neutral core; and
- (b) an active coating containing lansoprazole base, said active coating being layered over said neutral core to form a coated core;
- (c) a subcoating layer for coating said coated core, said subcoating layer comprising an alkaline agent; and
- (d) an enteric coating material layered over said subcoating layer; wherein said active coating is characterized in that said active coating does not include an alkaline agent and such that the composition is in a form of a pellet.

52. (Withdrawn) The composition of claim 2, wherein said neutral core has a size in a range of from about 80 to about 1000 microns.

53. (Withdrawn) A stable composition for Lansoprazole, the composition comprising:

- (a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;
- (b) a subcoating layer comprising an alkaline agent;
- (c) an enteric coating material layered over said subcoating layer to form enteric coated pellets;

{B0544290; 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 10 of 22

wherein said enteric coated pellets are compressed into a tablet dosage form.

54. (Withdrawn) The composition of claim 53, wherein said substrate features:

- i) a neutral core; and
  - ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;
- such that the composition is in a form of a pellet.

55. (Withdrawn) The composition of claim 54, wherein said neutral core has a size in a range of from about 80 to about 500 microns.

56. (Withdrawn) The composition of claim 55, wherein said size is in a range of from about 200 to about 300 microns.

57. (Withdrawn) The composition of claim 53, wherein said enteric coating does not include a plasticizer.

58. (New) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

- (a) a substrate, said substrate comprising an active core containing lansoprazole or a pharmaceutically suitable salt thereof as sole active ingredient and a surfactant, wherein said substrate is characterized in that said substrate does not include an alkaline agent;
- (b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and
- (c) an enteric coating material layered over said subcoating layer.

{B0544290: 1}

Application Serial No.: 10/575,809  
Reply to Office Action of June 23, 2008  
Reply Date of December 22 2008  
Page 11 of 22

59. (New) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising

i) a neutral core; and

ii) an active coating containing lansoprazole or a pharmaceutically suitable salt thereof as sole active ingredient and a surfactant, said active coating being layered over said neutral core, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer.

{B0544290: 1}